IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

JOSEPH MACALUSO,	§	
	§	
Plaintiff,	§	
	§	
V.	§	Civil Action No.: 3:17-cv-00542
	§	
ETHICON, INC., JOHNSON & JOHNSON,	§	
INC. and HOUSTON NORTHWEST	§	
OPERATING COMPANY, LLC d/b/a	8	
HOUSTON NORTHWEST MEDICAL	8	
CENTER,	8	
- ',	8	
Defendants.	§	

INDEX OF DOCUMENTS FILED IN STATE COURT

Exhibit	<u>Date</u>	Description of Document
A-1	Jan. 30, 2017	Plaintiff's Original Petition
A-2	Jan. 30, 2017	Civil Case Information Sheet
A-3	Jan. 30, 2017	Letter requesting issuance of citation for service of Plaintiff's Original Petition on: (1) Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center and (2) Ethicon, Inc.
A-4	Jan. 31, 2017	Letter re: payment of additional \$2 for necessary copies re: issuance of citation(s)
A-5	Feb. 3, 2017	Issuance of citation on Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center
A-6	Feb. 3, 2017	Issuance of citation on Ethicon, Inc.
A-7	Feb. 9, 2017	Service of citation on Ethicon, Inc. (Officer's Return, filed Feb. 10, 2017)

Exhibit	<u>Date</u>	<u>Description of Document</u>
A-8	Feb. 9, 2017	Service of citation on Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center (Officer's Return, filed Feb. 10, 2017)
A-9	Feb. 13, 2017	Defendant Houston Northwest Operating Company, LLC d/b/a Houston Northwest Medical Center's Original Answer
A-10	Feb. 23, 2017	Defendant Ethicon, Inc.'s Motion to Transfer Venue, and Subject Thereto, Original Answer and Defenses
A-11	Feb. 24, 2017	Docket sheet current as of date of filing of removal

Marissa Pittman

CAUSE NO. _____

DC-17-01163

JOSEPH MACALUSO	§	IN THE DISTRICT COURT
	§	
Plaintiff	§	
V.	§	
	§	JUDICIAL DISTRICT
ETHICON INC.,	§	
JOHNSON & JOHNSON, INC.	§	
And HOUSTON NORTHWEST CENTER	8	
URGENT CARE d/b/a HOUSTON NORTHWEST	8	
MEDICAL CENTER	§	
	§	
	§	
Defendants	§	DALLAS COUNTY, TEXAS

PLAINTIFF'S ORIGINAL PETITION

TO HONORABLE JUDGE OF SAID COURT:

Comes now Plaintiff, JOSEPH MACALUSO, by and through undersigned counsel, and bring this action against Defendants Ethicon, Inc., Johnson & Johnson and Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center (hereinafter "Defendants"), and allege as follows:

Discovery Control Plan and Rule 47 Allegations

This matter is appropriate for a Level III discovery control plan and damages to Plaintiff are at least \$1,000,000.

Parties

- 1. Plaintiff is, and was, at all relevant times, a citizen and resident of Texas and the United States.
- 2. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and

- Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 6 of 68 PageID 24 diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.
- 3. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.
- 4. Defendant Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon, Inc. is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is authorized and registered to transact business within the State of Texas, and its registered agent is CT Corp System who should be served via certified mail return receipt requested at 1999 Bryan St., Ste. 900 Dallas, Texas 75201. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Proceed (hereinafter may be referred to as the "product").
- 5. Defendant, Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center, is a Texas Limited Liability Company which may be served by serving its registered agent for service CT Corporation via certified mail at 1999 Bryan Street, 900, Dallas, Texas.

- 6. J&J, directly and/or through the actions of Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Proceed.
- 7. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.
- 8. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

Jurisdiction and Venue

- 9. Defendant, Houston Northwest Operating Company, L.L.C. d/b/a Houston
 Northwest Medical Center sold the Proceed to Plaintiff. Defendant Houston Northwest
 Operating Company, L.L.C.'s principle place of business is and was at all times hereto located in
 Dallas, County Texas at 1445 Ross Avenue Dallas, Texas 75201. Venue is proper in this Court
 as Defendant Houston Northwest Operating Company is located in Dallas County.
- 10. This Court has personal jurisdiction over each of the Defendants pursuant to the Texas Long-Arm Statute, Tex. Civ. Prac. Rem. Code § 17.042. Defendants transact business within the State of Texas, contracted to sell and supply their Proceed products in the State of Texas, and committed tortious acts and omissions in Texas. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Texas. Defendants employ sales

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 8 of 68 PageID 26 representatives in the State of Texas to sell their Proceed products throughout the State, including the Proceed implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Proceed products in Texas, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective mesh products, including Proceed, would be sold and implanted in Texas and could cause injury in Texas.

11. Ethicon, Inc. is registered to transact business in Texas.

Facts Common To All Counts

- 12. On or about July 8, 2013, Plaintiff Joseph Macaluso underwent laparoscopic ventral hernia repair performed by Dr. Philip Leggett at Houston Northwest Medical Center. Dr. Leggett utilized a 4.3 cm circular Proceed to repair the hernia.
- 13. Defendants manufactured, sold, and/or distributed the Proceed device to Plaintiff, through his doctors, to be used for treatment of hernia repair.
- 14. On or about January 28, 2015, Plaintiff Joseph Macaluso was admitted to Houston Northwest Medical Center and diagnosed with a severe hernia mesh infection and an acute kidney injury. Plaintiff then underwent placement of a PICC line for the administration of antibiotics. Plaintiff was discharged February 6, 2015, on home IV antibiotics. Plaintiff has been advised that the Proceed needs to be removed, but that the surgery would be very complicated due to the Proceed attaching to Plaintiff's intestines.
- 15. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Proceed, including providing the warnings and instructions concerning the product.

- Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 9 of 68 PageID 27 16. Among the intended purposes for which Defendants designed, manufactured and sold Proceed for use by surgeons for hernia repair surgeries, the purpose for which the Proceed
- 17. Defendants represented to Plaintiff and Plaintiff's physicians that Proceed was a safe and effective product for hernia repair.

was implanted in Plaintiff Joseph Macaluso.

- 18. Defendants' Proceed was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Proceed, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.
- 19. Proceed has a unique design incorporating a layer of oxidized regenerated cellulose (ORC) over a layer of polydioxanone, which in turn coats a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

- Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 10 of 68 PageID 28 20. The ORC layer of the Proceed has a tendency to delaminate from the other layers of the mesh, resulting in an air pocket (empty space), which leads to the formation of a seroma as the body fills the empty space with fluid. Seroma formation increases the risk of infection, abscess formation and other complications.
- 21. When affixed to the body's tissue, the impermeable multi-layer coating of the Proceed prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.
- 22. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.
- 23. The multi-layer coating of Defendants' Proceed is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.
- 24. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Proceed prior to introducing it into the stream of commerce.
- 25. When the multi-layer coating of the Proceed is disrupted, delaminates, and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, cause damage to organs, and potentiate fistula formation.
- 26. On or about December 2005, and again on or about October 2010, Defendants recalled approximately 20,000 Proceeds due to the ORC layer delaminating from the polypropylene mesh and the subsequent increased risk of adhesions and bowel fistulization.

 Defendants have been aware of the life-threatening issue of the Proceed delaminating for over a decade and continue to manufacture and market the Proceed as safe.

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- 27. These manufacturing and design defects associated with the Proceed were directly and proximately related to the injuries suffered by Plaintiff Joseph Macaluso.
- 28. Neither Plaintiff Joseph Macaluso nor his implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Proceed. Moreover, neither Plaintiff Joseph Macaluso nor his implanting physician were adequately warned or informed by Defendants of the risks associated with the Proceed or the frequency, severity, or duration of such risks.
- 29. The Proceed implanted in Plaintiff Joseph Macaluso failed to reasonably perform as intended. The mesh caused serious injury resulting in an extended hospitalization and Plaintiff will require additional invasive surgery to repair the hernia that the Proceed was initially implanted to treat.
- 30. Plaintiff Joseph Macaluso's severe adverse reaction, and the necessity for surgical removal of the Proceed, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Joseph Macaluso has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

COUNT I <u>Strict Product Liability: Defective Manufacture</u>

31. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

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- 32. Defendants expected and intended the Proceed product to reach users such as Plaintiff Joseph Macaluso in the condition in which the product was sold.
- 33. The implantation of Proceed in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.
- 34. At the time the Proceed that was implanted in Plaintiff's body, the product was defectively manufactured.
- 35. Defendants' manufacturing and quality control/assurance non-compliance resulted in the non-conformance of the Proceed implanted in Plaintiff Joseph Macaluso with intended manufacturing and design specifications.
- 36. The multi-layer coating of the Proceed also failed to conform to the Defendants' specifications in terms of shelf-life, thickness, durability, and quality.
- 37. Upon information and belief, Defendants' utilized adulterated polypropylene to manufacture Proceed.
- 38. Upon information and belief, Defendants' utilized adulterated cellulose to manufacture the Proceed.
- 39. As a direct and proximate result of the defective manufacture of the Proceed, Plaintiff suffered injuries and damages as summarized herein.

COUNT II Strict Product Liability: Defective Design

- 40. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.
- 41. At the time the Proceed that was implanted in Plaintiff Joseph Macaluso's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended,

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 13 of 68 PageID 31 and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

- 42. Defendants expected and intended the Proceed product to reach users such as Plaintiff in the condition in which the product was sold.
- 43. The implantation of Proceed in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.
- 44. The risks of the Proceed significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, enables the formation of dense adhesions to underlying organs, leading to bowel obstructions, fistulas, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.
- 45. The multi-layer coating of the Proceed, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. The coating itself does not prevent adhesions. Furthermore, the coating resorbs over time, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

- Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 14 of 68 PageID 32 46. The polypropylene mesh within the defective multi-layer coating of the Proceed was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Proceed. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Proceed, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.
- 47. Proceed is sterilized with gamma irradiation, which oxidizes the cellulose, creating oxidized regenerated cellulose (ORC). Cellulose is not bioresorbable in humans until it has undergone oxidation. The complex oxidation process often results in non-homogenous materials, parts of which are unable to be bioresorbed.
- 48. Proceed is the only polypropylene hernia mesh currently on the market to utilize gamma irradiation for sterilization of the entire hernia mesh. Gamma irradiation causes polypropylene to significantly degrade, and the degradation continues for a long time after the actual sterilization event. Gamma irradiation induced polypropylene degradation results in severe embrittlement of the polypropylene.
- 49. The ORC layer of Proceed is compromised in the presence of blood or where there is prolonged fibrin deposition due to inflammation. Fibrin is able to readily penetrate ORC and gain access to the base polypropylene. It is this fibrin bridging which initiates adhesion formation. The polypropylene component of Proceed incites a chronic inflammatory response, leading to prolonged fibrin deposition.
- 50. The appropriate treatment for complications associated with Proceed involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

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- 51. Proceed was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.
- 52. At the time the Proceed was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.
- 53. The Proceed product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.
- 54. The Proceed implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.
- 55. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT III Strict Product Liability: Failure to Warn

- 56. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.
- 57. At the time the Proceed that was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

- Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 16 of 68 PageID 34 58. Defendants expected and intended the Proceed product to reach users such as Plaintiff in the condition in which the product was sold.
- 59. Plaintiff and his physicians were unaware of the defects and dangers of Proceed, and were unaware of the frequency, severity and duration of the defects and risks associated with the Proceed.
- on the Defendants' Instructions for Use provided with the Proceed expressly understates and misstates the risks known to be associated specifically with the Proceed by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States and no other "surgically implantable material" suffers the same serious design flaws as Proceed. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including dense adhesions, seroma formation, immunologic response, infection, inflammatory reaction, and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Proceed.
- 61. The Defendants' Instructions for Use for the Proceed failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Proceed, including the risks of the product's inability to reduce dense adhesions to internal organs and viscera, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.

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- 62. Defendants failed to adequately train or warn Plaintiff or his physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.
- 63. Defendants failed to adequately warn Plaintiff or his physicians that the necessary surgical removal of the Proceed in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Proceed was intended to treat.
- 64. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Proceed to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating would be ineffective in the presence of blood or fibrin, both of which are present during and/or after implantation. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.
- 65. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Proceed were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.
- 66. If Plaintiff and/or his physicians had been properly warned of the defects and dangers of Proceed, and of the frequency, severity and duration of the risks associated with the

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 18 of 68 PageID 36 Proceed, Plaintiff would not have consented to allow the Proceed to be implanted in his body, and Plaintiff physicians would not have implanted the Proceed in Plaintiff.

67. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV Negligence

- 68. Plaintiffs incorporate herein by reference the allegations in all prior Paragraphs as if fully set forth herein.
- 69. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Proceed, but failed to do so.
- 70. Defendants knew, or in the exercise of reasonable care should have known, that Proceed was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Proceed was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Proceed.
- 71. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Proceed, Plaintiffs suffered injuries and damages as summarized herein.

Count V Breach of the Warranty of Merchantability

72. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein. Defendants sold the Proceed to Plaintiff, Joseph Macaluso. Said product was unfit for its ordinary purpose because of the defects alleged above in violation of the implied PLAINTIFF'S ORGINAL PETITION

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 19 of 68 PageID 37 warranty of merchantability. Said violation proximately Joseph Macaluso caused severe personal injury that resulted in damages hereinafter described.

Count VI Violation of the Texas Deceptive Trade Practices Act

73. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein. Plaintiff was a consumer of the Proceed under the Texas Deceptive Trade Practice Act. Plaintiff hereby brings a claim under the Texas Bus. & Com. Code \$17.50(a)(2) for the aforementioned breach of implied warranty of merchantability mentioned above. Plaintiff seek reliefs provided for under Tex. Bus. Com. Code \$17.50 (b) for economic damages for breaches of said warranty. Furthermore, Defendants knowingly breached said warranty as they knew the Proceed was not fit for the ordinary purposes. Plaintiff seeks mental anguish damages and treble of economic damages for said knowing conduct. Additionally, Plaintiff seeks reasonable and necessary attorney's fees as well as costs.

Count VII Punitive Damages

- 74. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.
- 75. Defendants failed to adequately test and study the Proceed to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Proceed after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Proceed, Defendants developed, designed and sold Proceed, and continue to do so, because the Proceed has a significantly higher profit margin than other hernia repair products.

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 20 of 68 PageID 38 Defendants were aware of the probable consequences of implantation of the dangerous and defective Proceed, including the risk of failure and serious injury, such as suffered by Plaintiff. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard the safety of those persons who might foreseeably have been harmed by the Proceed product, including Plaintiff, justifying the imposition of punitive damages.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Joseph Macaluso is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; and past, present and future mental and physical pain and suffering; and Plaintiff should be awarded punitive damages as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

Plaintiff demands, judgment against Defendants, jointly and severally, for compensatory and punitive damages, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

Respectfully submitted,

Brock & Goetzmann, PLLC

By: /s/ Tamara Brock Segal

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CIVIL CASE INFORMATION SHEET

FILED DALLAS COUNTY 1/30/2017 3:40:50 PM FELICIA PITRE

DISTRICT CLERK

Filed 02/24/17 PageID 41

Case 3:17-cv-00542-M. Dogument 1-3 4/17 Page 23 of 68 COURT (FOR CLERK USE ONLY): _

Joseph Macaluso v. Ethicon, Inc., Johnson & Johnson, Inc. and Houston Northwest Medical Center Marissa Pittman STYLED

(e.g., John Smith v. All American Insurance Co; In re Mary Ann Jones; In the Matter of the Estate of George Jackson)

A civil case information sheet must be completed and submitted when an original petition or application is filed to initiate a new civil, family law, probate, or mental health case or when a post-judgment petition for modification or motion for enforcement is filed in a family law case. The information should be the best available at the time of filing.

1. Contact information for perso	n completing case information she	et:	Names of parties in	n case:		Person	or entity completing sheet is:
Name:	Email: P		Plaintiff(s)/Petitioner(s):		☐ Attorney for Plaintiff/Petitioner ☐ Pro Se Plaintiff/Petitioner ☐ Title IV-D Agency		
Stephen Goetzmann	Stephen@Brockgoetzmann.c	com_	_Joseph Macaluso_			Other:	
Address:	Telephone:					Addition	al Parties in Child Support Case:
~9400 N. Central Expway Suite 4	16214-458-0190		Defendant(s)/Basna	D.C. 1. (()(D			
City/State/Zip:	Fax:		Defendant(s)/Respondent(s): Ethicon, Inc		Custodial	Parent:	
Dallas, Texas 75231	214-739-1496		Johnson & Johnson, Inc		Non-Cust	todial Parent:	
Signature:	State Bar No:		Houston Northwest Medical Ctr Inc		Presumed	l Father:	
_/s/Stephen Goetzmann	08059850			Houston Northwest Medical Ctr Inc Presumed Father: [Attach additional page as necessary to list all parties]			
2. Indicate case type, or identify	the most important issue in the cas	se (select	t only 1):				
	Civil					Fam	ily Law
Contract	Injury or Damage		Real Property	Marr	iage Relati	onship	Post-judgment Actions (non-Title IV-D)
Debt/Contract	Assault/Battery		inent Domain/	Ann	ulment		☐ Enforcement
☐Consumer/DTPA ☐Debt/Contract	☐ Construction ☐ Defamation	Con	ndemnation	☐Dec Divorc	lare Marria	ge Void	☐ Modification—Custody ☐ Modification—Other
Fraud/Misrepresentation	Malpractice	Qui	iet Title	□V	Vith Childre		Title IV-D
Other Debt/Contract:	☐Accounting ☐Legal	Tre	spass to Try Title her Property:		lo Children	l	Enforcement/Modification
Foreclosure	☐ Medical		ier Froperty.	_			☐ Paternity ☐ Reciprocals (UIFSA)
☐ Home Equity—Expedited	Other Professional						Support Order
☐ Other Foreclosure ☐ Franchise	Liability:	Re	elated to Criminal				
☐Insurance	Motor Vehicle Accident		Matters		her Family		Parent-Child Relationship
☐ Landlord/Tenant☐ Non-Competition	☐ Premises Product Liability		ounction gment Nisi		orce Foreig	gn	Adoption/Adoption with Termination
☐ Partnership	Asbestos/Silica	□Not	n-Disclosure	□Hab	eas Corpu	S	Child Protection
Other Contract:	☑Other Product Liability		zure/Forfeiture it of Habeas Corpus—	□Nar	ne Change tective Ord		☐ Child Support☐ Custody or Visitation
	List Product: Hernia Mesh		it of Habeas Corpus— indictment		noval of Di		Gestational Parenting
	Other Injury or Damage:	Oth	ner:		Minority		Grandparent Access
				Oth	er:		☐ Parentage/Paternity ☐ Termination of Parental
Employment	Other	Civil					Rights
Discrimination	Administrative Appeal	Lav	vyer Discipline				Other Parent-Child:
Retaliation	Antitrust/Unfair	Per	petuate Testimony curities/Stock				
☐ Termination ☐ Workers' Compensation	Competition ☐Code Violations		tious Interference				
Other Employment:	Foreign Judgment	Oth	ner:	-			
	☐Intellectual Property						
Tax	Probate & Mental Health						
☐Tax Appraisal	Probate/Wills/Intestate Administr	ration		Guardian	ship—Adu		
☐ Tax Delinquency ☐ Other Tax	☐ Dependent Administration ☐ Independent Administration	,		☐Guardian: ☐Mental H	1	or	
Outer Tax	Other Estate Proceedings	1		Other:			_
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FILED DALLAS COUNTY 30/2017 3:40:50 PM

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 25 of 68 PageID 43

DISTRICT CLERK

Marissa Pittman



9400 North Central Expressway, Suite 416 Dallas, Texas 75231 Fax: (214) 739-1496

Tamara Brock Segal (972)757-1717 Email: tamara@brockgoetzmann.com Stephen R. Goetzmann (214) 458-0190 Email: stephen@brockgoetzmann.com

DC-17-01163

January 30, 2017

Felicia Petire Dallas County District Clerk 600 Commerce St # 103, Dallas, TX 75202

RE: Cause	, Joseph Macaluso v. Ethicon Inc, Johnson & Johnson,
Inc. and Houston	Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical
Center. In the	Judicial District Court of Dallas County, Texas.

Dear District Clerk,

- 1. Please issue a citation to for service to *Houston Northwest Operating Company*, *L.L.C. d/b/a Houston Northwest Medical Center*, their Registered Agent for Service CT Corporation System 1999 Bryan Street, 900, Dallas, Texas 75201 *via* certified mail return receipt requested.
- 2. Please issue a citation to for service to Ethicon, Inc. to their Registered Agent for Service CT Corporation System 1999 Bryan Street, 900, Dallas, Texas 75201 *via* certified mail return receipt requested.

Please provide these and copies of the Original Petition in the for service by the Dallas County Constable or other agency who serves process via certified mail.

If you have any questions, please do not hesitate to contact us at the numbers above or via email. Thank you.

Sincerely,

Tamara Brock Segal

DISTRICT CLERK

Tonya Pointer



9400 North Central Expressway, Suite 416 Dallas, Texas 75231 Fax: (214) 739-1496

Tamara Brock Segal (972)757-1717 Email: tamara@brockgoetzmann.com Stephen R. Goetzmann (214) 458-0190 Email: stephen@brockgoetzmann.com

January 31, 2017

Felicia Petire Dallas County District Clerk 600 Commerce St # 103, Dallas, TX 75202

> RE: Cause DC-17-01163, Joseph Macaluso v. Ethicon Inc, Johnson & Johnson, Inc. and Houston Northwest Operating Company, L.L.C. d/b/a Houston Northwest Medical Center. In the 95th Judicial District Court of Dallas County, Texas.

Dear District Clerk,

Payment for copies of 16 pages times two or \$32 was made. Apparently 1 blank page was attached inadvertently. I'm hereby paying an additional \$2 for this error.

If you have any questions, please do not hesitate to contact us at the numbers above or via email. Thank you.

Sincerely,

Tamara Brock Segal

FORM NO. 353-3 - CITATION THE STATE OF TEXAS

To:

HOUSTON NORTHWEST OPERATING COMPANY L.L.C. D/B/A HOUSTON NORTHWEST MEDICAL CENTER BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM 1999 BRYAN ST STE 900 DALLAS TX 75201

GREETINGS:

You have been sued. You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10 o'clock a.m. of the Monday next following the expiration of twenty days after you were served this citation and petition, a default judgment may be taken against you. Your answer should be addressed to the clerk of the 95th District Court at 600 Commerce Street, Ste. 101, Dallas, Texas 75202.

Said Plaintiff being JOSEPH MACALUSO

Filed in said Court 30th day of January, 2017 against

ETHICON INC., JOHNSON & JOHNSON, INC. AND HOUSTON NORTHWEST CENTER URGENT CARE D/B/A HOUSTON NORTHWEST MEDICAL CENTER

For Suit, said suit being numbered <u>DC-17-01163</u>, the nature of which demand is as follows: Suit on **OTHER** (**CIVIL**) etc. as shown on said petition, a copy of which accompanies this citation. If this citation is not served, it shall be returned unexecuted.

WITNESS: FELICIA PITRE, Clerk of the District Courts of Dallas, County Texas. Given under my hand and the Seal of said Court at office this 3rd day of February, 2017.

ATTEST: FELICIA PITRE, Clerk of the District Courts of Dallas, County, Texas

KERRY KALLIE

Colie Deputy

CERT MAIL

CITATION

DC-17-01163

JOSEPH MACALUSO vs. ETHICON INC, et al

ISSUED THIS 3rd day of February, 2017

> FELICIA PITRE Clerk District Courts, Dallas County, Texas

By: KERRY KALLIE, Deputy

Attorney for Plaintiff
TAMARA SEGAL
9400 N CENTRAL EXPWY
SUITE 416
DALLAS TX 75231
214-739-1831

PAID PAID

OFFICER'S RETURN

Case No.: DC-17-01163					
Court No.95th District Co	ourt				
Style: JOSEPH MACALU	JSO				
vs.					
ETHICON INC, et al					
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	For serving Citation	s	44-14-14		
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FORM NO. 353-3 - CITATION THE STATE OF TEXAS

To:

ETHICON INC.
BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM
1999 BRYAN ST STE 900
DALLAS TX 75201

GREETINGS:

You have been sued. You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10 o'clock a.m. of the Monday next following the expiration of twenty days after you were served this citation and petition, a default judgment may be taken against you. Your answer should be addressed to the clerk of the 95th District Court at 600 Commerce Street, Ste. 101, Dallas, Texas 75202.

Said Plaintiff being JOSEPH MACALUSO

Filed in said Court 30th day of January, 2017 against

ETHICON INC., JOHNSON & JOHNSON, INC. AND HOUSTON NORTHWEST CENTER URGENT CARE D/B/A HOUSTON NORTHWEST MEDICAL CENTER

For Suit, said suit being numbered <u>DC-17-01163</u>, the nature of which demand is as follows: Suit on **OTHER (CIVIL)** etc. as shown on said petition, a copy of which accompanies this citation. If this citation is not served, it shall be returned unexecuted.

WITNESS: FELICIA PITRE, Clerk of the District Courts of Dallas, County Texas. Given under my hand and the Seal of said Court at office this 3rd day of Pebruary, 2017.

ATTEST: FELICIA PITRE, Clerk of the District Courts of Dallas, County, Texas

VEDBY KALLE

Deputy

CERT MAIL

CITATION

DC-17-01163

JOSEPH MACALUSO vs. ETHICON INC, et al

ISSUED THIS 3rd day of February, 2017

> FELICIA PITRE Clerk District Courts, Dallas County, Texas

By: KERRY KALLIE, Deputy

Attorney for Plaintil'
TAMARA SEGAL
9400 N CENTRAL EXPWY
SUITE 416
DALLAS TY 75221
214-739-1831

PAID PAID

OFFICER'S RETURN

Case No.: DC-17-01163							
Court No.95th District Co	ourt						
Style: JOSEPH MACALU	JSO						
vs.							
ETHICON INC, et al							
Came to hand on the	day of	, 20	, at	o'clock	M. Executed at		
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Signed and sworn to by th	ne said	before me th	isday of		, 20,		
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OFFICER'S RETURN

FILED

17 FEB 10 AM 9: 01 Court No.95th District Court Style: JOSEPH MACALUSO VS. ETHICON INC, et al day of February 20 17 at 8:15 o'clock Dallas 9:41 o'clock___ A.M. on the within the County of , by delivering to the within named each, in person, a true copy of this Citation together with the accompanying copy of this pleading, having first endorsed on same date of delivery. The distance actually traveled by me in serving such process was miles and my fees are as follows: To certify which witness my hand.

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	For Notary	S	By Ker	ry Kallie	DEFELICIA PITRE
		(Must be verified if	served outside the State	of Texas.)	DISTRICT CLERK 600 COMMERCE STREET
Signed and sworn to by the	said	before me this	day of	, 20,	DALLAS, TEXAS 75202-460
to certify which witness my	hand and seal of office.				

Case No.: DC-17-01163

Notary Public County

FORM NO. 353-3 - CITATION THE STATE OF TEXAS

To:

ETHICON INC.
BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM
1999 BRYAN ST STE 900
DALLAS TX 75201

GREETINGS:

You have been sued. You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10 o'clock a.m. of the Monday next following the expiration of twenty days after you were served this citation and petition, a default judgment may be taken against you. Your answer should be addressed to the clerk of the 95th District Court at 600 Commerce Street, Ste. 101, Dallas, Texas 75202.

Said Plaintiff being JOSEPH MACALUSO

Filed in said Court 30th day of January, 2017 against

ETHICON INC., JOHNSON & JOHNSON, INC. AND HOUSTON NORTHWEST CENTER URGENT CARE D/B/A HOUSTON NORTHWEST MEDICAL CENTER

For Suit, said suit being numbered <u>DC-17-01163</u>, the nature of which demand is as follows: Suit on **OTHER (CIVIL)** etc. as shown on said petition, a copy of which accompanies this citation. If this citation is not served, it shall be returned unexecuted.

WITNESS: FELICIA PITRE, Clerk of the District Courts of Dallas, County Texas. Given under my hand and the Seal of said Court at office this 3rd day of Pebruary, 2017.

ATTEST: FELICIA PITRE, Clerk of the District Courts of Dallas, County, Texas

KERRYKALIT

, Deputy

CERT MAIL

CITATION

DC-17-01163

JOSEPH MACALUSO vs. ETHICON INC, et al

ISSUED THIS 3rd day of February, 2017

FELICIA PITRE Clerk District Courts, Dallas County, Texas

By: KERRY KALLIE, Deputy

Attorney for Plainted
TAMARA SLOAL
9400 N CENTRAL EXPWY
SUITE 416
DALLAS TV 75221
214-739-1351

PAIL FEES NOT

Date: February 9, 2017

POSTAL SERVICE.

MAIL MAIL:

The following is in response to your February 9, 2017 request for delivery information on your Certified Mail™/RRE item number 92148901066154000102244506. The delivery record shows that this item was delivered on February 9, 2017 at 9:41 am in DALLAS, TX 75201. The scanned image of the recipient information is provided below.

Signature of Recipient:

Christoper Uills

Address of Recipient:

C.T. Corp 250 M.Sal

Thank you for selecting the Postal Service for your mailing needs.

If you require additional assistance, please contact your local Post Office or postal representative.

Sincerely, United States Postal Service

The customer reference information shown below is not validated or endorsed by the United States Postal Service. It is solely for customer use.

Reference ID: 92148901066154000102244506 DC1701163 ETHICON INC. BY SERVING ITS REGISTERED AGENT CT CORPORATION SYSTEM 1999 BRYAN STREET STE 900 DALLAS, TX 75201-0000 Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 38 of 68 PageID 56

FELICIA PITRE
DISTRICT CLERK
GEORGE L ALLEN SR COURT BLDG
600 COMMERCE ST STE 103
DALLAS, TX 75202-4689



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RETURN RECEIPT (ELECTRONIC)

DC1701163

ETHICON INC.
BY SERVING ITS REGISTERED AGENT CT CORPORATION
SYSTEM
1999 BRYAN STREET STE 900
DALLAS, TX 75201

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EXHIBIT A-8

OFFICER'S RETURN

FILED

Case No.: DC-17-01163				17 FEB 10 AM 9: 00
Court No.95th District Court				FELLA PITRE
Style: JOSEPH MACALUSO				DALLASION TEXAS
vs.				OKPUTY
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to certify which witness my hand and seal of office.				DISTRICT CLERK
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		Notary Public	County_	

FORM NO. 353-3 - CITATION THE STATE OF TEXAS

To:

HOUSTON NORTHWEST OPERATING COMPANY L.L.C. D/B/A HOUSTON NORTHWEST MEDICAL CENTER BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM 1999 BRYAN ST STE 900 DALLAS TX 75201

GREETINGS:

You have been sued. You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10 o'clock a.m. of the Monday next following the expiration of twenty days after you were served this citation and petition, a default judgment may be taken against you. Your answer should be addressed to the clerk of the 95th District Court at 600 Commerce Street, Ste. 101, Dallas, Texas 75202.

Said Plaintiff being JOSEPH MACALUSO

Filed in said Court 30th day of January, 2017 against

ETHICON INC., JOHNSON & JOHNSON, INC. AND HOUSTON NORTHWEST CENTER URGENT CARE D/B/A HOUSTON NORTHWEST MEDICAL CENTER

For Suit, said suit being numbered <u>DC-17-01163</u>, the nature of which demand is as follows: Suit on **OTHER (CIVIL)** etc. as shown on said petition, a copy of which accompanies this citation. If this citation is not served, it shall be returned unexecuted.

WITNESS: FELICIA PITRE, Clerk of the District Courts of Dallas, County Texas. Given under my hand and the Seal of said Court at office this 3rd day of February, 2017.

ATTEST: FELICIA PITRE, Clerk of the District Courts of Dallas, County, Texas

KERRY KALLIH

, Deputy

CERT MAIL

CITATION

DC-17-01163

JOSEPH MACALUSO vs. ETHICON INC, et al

ISSUED THIS 3rd day of February, 2017

> FELICIA PITRE Clerk District Courts, Dallas County, Texas

By: KERRY KALLIE, Deputy

Attorney for Plaintiff
TAMARA SEGAL
9400 N CENTRAL EXPWY
SUITE 416
DALLAS TX 75231
214-739-1831

FEES FEES NOT PAID

Date: February 9, 2017

POSTAL SERVICE.

MAIL MAIL:

The following is in response to your February 9, 2017 request for delivery information on your Certified Mail™/RRE item number 92148901066154000102243455. The delivery record shows that this item was delivered on February 9, 2017 at 9:41 am in DALLAS, TX 75201. The scanned image of the recipient information is provided below.

Signature of Recipient:

Christopher Vills

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C.T. Corp 250 M.S.I

Thank you for selecting the Postal Service for your mailing needs.

If you require additional assistance, please contact your local Post Office or postal representative.

Sincerely, United States Postal Service

The customer reference information shown below is not validated or endorsed by the United States Postal Service. It is solely for customer use.

Reference ID: 92148901066154000102243455 DC1701163 DPRO KK HOUSTON NORTHWEST OPERATING COMPANY L.L.C. D/B/A HOUSTON NORTHWEST MEDICAL CENTER BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM 1999 BRYAN STREET STE 900 DALLAS, TX 75201-0000 Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 43 of 68 PageID 61

FELICIA PITRE DISTRICT CLERK GEORGE L ALLEN SR COURT BLDG 600 COMMERCE ST STE 103 DALLAS, TX 75202-4689



9214 8901 0661 5400 0102 2434 55

RETURN RECEIPT (ELECTRONIC)

DC1701163 DPRO KK

HOUSTON NORTHWEST OPERATING COMPANY L.L.C. D/B/A HOUSTON NORTHWEST MEDICAL CENTER BY SERVING REGISTERED AGENT CT CORPORATION SYSTEM 1999 BRYAN STREET STE 900 DALLAS, TX 75201

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EXHIBIT A-9

CAUSE NO. DC-17-01163

JOSEPH MACALUSO	§	IN THE DISTRICT COURT OF
	§	
V.	§	DALLAS COUNTY, TEXAS
	§	
ETHICON, INC., et al.	§	95 TH JUDICIAL DISTRICT COURT

DEFENDANT'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Defendant, Houston Northwest Operating Company LLC d/b/a Houston Northwest Medical Center, and in answer to Plaintiff's Original Petition, would show unto the court as follows:

I.

Defendant specially excepts to the failure of Plaintiff to plead compliance with conditions precedent.

II.

Defendant further specially excepts to the pleading of an ad damnum in Plaintiff's Rule 47 Allegation, which violates CPRC section 74.053. Defendant would show itself entitled to an order striking said improper pleading.

III.

Defendant specially excepts to all unsegregated products liability allegations in paragraphs 15 though 71. Defendant would show that none of these allegations are appropriate against a hospital where a product was used by a surgeon during surgery, and Defendant is entitled to an order striking the inapplicable pleadings against it.

IV.

Defendant further specially excepts to paragraph 72, Breach of Warranty, and 73, Deceptive Trade Practices, for the same grounds enunciated in paragraph III and because, statutorily, said claims do not lie against a hospital wherein a surgeon used a product during surgery. Defendant would show itself entitled to an order striking said inapplicable pleadings.

V.

Defendant further specially excepts to the general, conclusory, and unsegregated allegations of gross negligence in paragraph 74. Defendant would show itself entitled to a segregation of said allegations among the Defendants and to a specific pleading of each individual act allegedly giving rise to a claim of gross negligence against an entity Defendant.

VI.

Subject to the foregoing special exceptions, without waiving same, Defendant denies generally the allegations of Plaintiff's Original Petition and demands strict proof thereof.

VII.

Defendant would further show that Plaintiff failed to give and plead Notice pursuant to Chapter 74 of the Civil Practice and Remedies Code.

VIII.

Defendant would further show that Plaintiff's claim is barred by the applicable statute of limitations. By Plaintiff's admission in the factual recitation of his petition, the mesh was inserted 7-8-13 and was infected, with systemic complications, on 1-28-15. On that date, well within the statute of limitations, Plaintiff was aware of potential injury from the mesh and he failed to file suit within 2 years of the occurrence of the alleged tort.

IX.

Defendant, as permitted by Rule 92 of the Texas Rules of Civil Procedure, denies generally the allegations of Plaintiff's Original Petition and demands strict proof thereof.

X

Defendant specifically denies that Plaintiff is entitled to a recovery. However, in the unlikely event of a recovery, Defendant would show itself entitled to the damage limitations contained in the Civil Practice and Remedies Code.

WHEREFORE, PREMISES CONSIDERED, Defendant moves and prays that upon due hearing, its special exceptions be sustained and that, upon final hearing, Plaintiff take nothing and Defendant go hence with costs, plus such other and further relief to which it may show itself justly entitled to receive.

Respectfully submitted,

COOKSEY & MARCIN, PLLC

25511 Budde Road #2202, El Paso Building The Woodlands, Texas 77380 (281) 719-5881 Telephone (281) 719-5847 Facsimile

By: /S/ CHRISTINA CONNOR HUSTON

Curry L. Cooksey State Bar No. 04762400 ccooksey@cookseymarcinlaw.com Christina Connor Huston State Bar No. 45007043 chuston@cookseymarcinlaw.com

ATTORNEYS FOR DEFENDANT HOUSTON NORTHWEST OPERATING COMPANY, LLC D/B/A HOUSTON NORTHWEST MEDICAL CENTER

CERTIFICATE OF SERVICE

I do hereby certify that a true and correct copy of the above and foregoing instrument has been served on all counsel of record via electronic filing and facsimile and/or Certified Mail/RRR mail on this the 13th day of February, 2017 to:

Tamara Brock Segal Stephen R. Goetzmann Brock & Goetzmann, PLLC 9400 N. Central Expressway Suite 416 Dallas, Texas 75231

via facsimile 214-739-1496

/S/ CHRISTINA CONNOR HUSTON

EXHIBIT A-10

DISTRICT CLERK

CAUSE NO. DC-17-01163

JOSEPH MACALUSO,	§	IN THE DISTRICT COURT
	§	
Plaintiff,	§	
V.	§	95 TH JUDICIAL DISTRICT
	§	
ETHICON, INC., JOHNSON	§	
& IOHNSON INC And	Š	

& JOHNSON, INC. And 3 § § § § § HOUSTON NORTHWEST CENTER URGENT CARE d/b/a HOUSTON NORTHWEST MEDICAL CENTER,

Defendants. DALLAS COUNTY, TEXAS

DEFENDANT ETHICON, INC.'S MOTION TO TRANSFER VENUE, AND SUBJECT THERETO, ORIGINAL ANSWER AND DEFENSES

Defendant Ethicon, Inc. files this motion to transfer venue, and subject thereto, its answer to Plaintiff's Original Petition ("Petition") filed by Plaintiff Joseph Macaluso. In support, Ethicon respectfully shows the Court the following:

I. MOTION TO TRANSFER VENUE

- 1. Ethicon objects to venue in Dallas County, Texas, where Plaintiff filed suit, because there is a more convenient and just venue. Specifically, Harris County is the more convenient venue, and therefore, this case should be transferred from Dallas County, Texas to Harris County, Texas.
- 2. Plaintiff alleges that venue is proper in this court because "Defendant Houston Northwest Operating Company, L.L.C.'s principle [sic] place of business is and was at all times hereto located in Dallas, County Texas " Plf.'s Orig. Pet. ¶ 9. Thus, Plaintiff's choice of venue is based on the permissive venue statute. Tex. Civ. Prac. & Rem. Code § 15.001(2)(a). Ethicon specifically denies that Defendant Houston Northwest Operating Company, L.L.C.'s principal place of business is in Dallas County, Texas and therefore, venue is improper in Dallas

DEFENDANT ETHICON, INC.'S MOTION TO TRANSFER VENUE, AND SUBJECT THERETO, ORIGINAL ANSWER AND DEFENSES — PAGE 1

County for this reason. Furthermore, based on the allegations in Plaintiff's Petition, it is clear that all of the events at issue occurred in Harris County, Texas. Thus, under the factors set forth in Texas Civil Practice and Remedies Code § 15.002(b)(1)-(3) venue is more appropriate, convenient, and just in that jurisdiction.

3. Specifically, Plaintiff underwent two surgical procedures at Houston Northwest Medical Center, located in Houston, Texas. Plf.'s Orig. Pet. ¶¶ 12, 14. In addition, Plaintiff received his medical treatment from Houston surgeon Dr. Philip Leggett. *Id.* at ¶ 12. Thus, the evidence and witnesses likely to be relevant in this case are located in Harris County, Texas, and venue is proper and more convenient there. Tex. Civ. Prac. & Rem. Code § 15.002(a)(1). Moreover, because the facts giving rise to Plaintiff's lawsuit took place in Harris County, Texas, a transfer would not work an injustice on any party. Tex. Civ. Prac. & Rem. Code § 15.002(b)(3). Accordingly, this case should be transferred to Harris County, Texas in the interest of justice and for the convenience of the parties and witnesses.

II. GENERAL DENIAL

4. In accordance with Rule 92 of the Texas Rules of Civil Procedure, and subject to its Motion to Transfer Venue, Defendant Ethicon generally denies each and every allegation and claim in the Plaintiff's Petition, and demands strict proof thereof.

III. DEFENSES

- 5. The Petition fails to state a cause of action upon which relief can be granted.
- 6. Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in Texas and any other state whose law is deemed to apply in this case.
 - 7. Plaintiff's claims are barred by the doctrine of federal preemption, as established

by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the products at issue are regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

- 8. At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and Plaintiff's claims are accordingly barred.
- 9. Plaintiff's claims against Ethicon are expressly or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).
- and federal statutes regarding the products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiff's claims are not barred, Ethicon is entitled to a presumption that the products at issue are free from any defect or defective condition, as the plans or design for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue or the methods and techniques

REM. CODE § 82.008.

- 11. Plaintiff's claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated there under.
- 12. Plaintiff's claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.
- 13. Any claims by Plaintiff's relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to petition the government.
- 14. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.
- 15. Plaintiff cannot state a claim with regard to warnings and labeling for medical devices, because the remedy sought by Plaintiff is subject to the exclusive regulation of FDA.
- 16. Plaintiff's claims are barred in whole or in part by Plaintiff's failure to assert a safer design for any of the products at issue.
- 17. Plaintiff's claims are barred in whole or in part because the products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were

provided.

- 18. The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of FDA.
- 19. At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.
- 20. Plaintiff's inadequate warning claims are barred because the alleged risk of which Plaintiff claim is open, obvious, or a matter of common knowledge.
- 21. Plaintiff's claims are barred in whole or in part because the products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.
- 22. Adequate and complete warnings and instructions were provided with the products at issue. The products at issue were neither defective nor unreasonably dangerous when used according to its Instructions for Use. Indeed, the warnings and instructions that accompanied the products in their distributions were those approved by the U.S. FDA for a product approved under the Federal Food, Drug and Cosmetic Act, as amended, or, section 351 Public Health Service Act, as amended, or, otherwise meet the presumption requirements in Tex. Civ. Prac. & Rem. Code § 82.007.
- 23. The presumptions in Tex. Civ. Prac. & Rem. Code §§ 82.007 and 82.08 apply in this case.

- 24. Plaintiff's causes of action are barred by the learned intermediary doctrine.
- 25. Ethicon is not liable to Plaintiff because the end users of the products at issue, Plaintiff's physician(s), were sophisticated users of the products.
- 26. Ethicon states that the sole proximate cause of the injuries and/or damages alleged by Plaintiff was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiff is not, therefore, entitled to recover from Ethicon in this action. As to Plaintiff or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiff, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault, and comparative negligence, as well as the provisions of any applicable comparative fault or comparative negligence or contributory negligence statute, law or policy of Texas and any other applicable state. Tex. Civ. Prac. & Rem. Code § § 33.001-33.016.
- 27. There is no causal relationship between Ethicon's conduct and the injuries and damages alleged by Plaintiff in the Petition. Some or all of Plaintiff's claims are barred by the doctrine of superseding, intervening, or new and independent cause.
- 28. Plaintiff's alleged injuries, losses, or damages attributable to the products at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility.
- 29. Some or all of Plaintiff's claims may be barred by the statutes of limitations or prescription, or statutes of repose of Texas or the applicable states.
- 30. The liability of Ethicon, if any, for Plaintiff's non-economic loss must be apportioned in accordance with the provisions of the law of Texas or the applicable states.

- 31. Ethicon expressly denies any third party engaging in the acts alleged by Plaintiff was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, Plaintiff's claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.
- 32. Plaintiff's causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic, or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, operation of nature, act of God, or preexisting condition, or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.
- 33. Plaintiff's claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel.
- 34. Plaintiff's alleged damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages.
- 35. The sale, labeling, and marketing of the products at issue in this litigation is not, and was not, likely to mislead or deceive the public.
- 36. The products at issue were substantially altered after the products left the control, custody and possession of Ethicon, and said substantial alteration was the sole cause if the products at issue became unreasonably dangerous. Therefore, the products at issue were not in a defective condition when sold by Ethicon.
- 37. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiff's Legal*

Committee, 531 U.S. 341 (2001).

- 38. Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.
- 39. Plaintiff's claims are barred in whole or in part under Section 402A, comment j and k of the Restatement (Second) of Torts.
- 40. Ethicon made no express or implied representations or warranties of any kind to Plaintiff, nor did Plaintiff rely on any representations or warranties made by Ethicon to others. To the extent Plaintiff relied upon any representations or warranties, such reliance was unjustified.
- 41. Any express or implied warranties alleged to have been made by Ethicon were disclaimed.
- 42. Ethicon did not make nor did it breach any express or implied warranties or breach any warranties created by law. To the extent that Plaintiff relied on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Plaintiff and Ethicon, or by Plaintiff's failure to give Ethicon timely notice of the alleged breach of warranty and an opportunity to cure. Ethicon further specifically pleads as to any breach of warranty claim all affirmative defenses available to Ethicon under the Uniform Commercial Code, as enacted in the State of Texas or any other state whose law is deemed to apply in this case, and under the common-law principles of Texas or any state whose law is deemed to apply in this case.
- 43. Ethicon specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Ethicon under the rules and statutes of Texas or any state whose law is deemed to apply in this case, and under the common-law

principles of Texas or any state whose law is deemed to apply in this case.

- 44. Plaintiff's claims are or may be barred by her failure to comply with conditions precedent to her right to recover.
- 45. Plaintiff's claim for punitive damages is barred because the products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the products at issue.
- 46. The Petition fails to state facts sufficient to entitle Plaintiff to an award of punitive damages.
- 47. Plaintiff's claims for medical or health care expenses are limited to the amount actually paid or incurred by or on her behalf, in accordance with section 41.0105 of the Texas Civil Practice and Remedies Code.
- 48. Any recovery by Plaintiff must be reduced or offset by all amounts paid, payable by, or available from collateral sources.
- 49. Plaintiff's Petition fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, or post-judgment interest.
- 50. No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred. TEX. CIV. PRAC. & REM. CODE § 41.003.
- 51. The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due-process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the excessive fines clause in the Eighth Amendment to the Constitution of the United States, and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States, and the equivalent or

correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that: is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or by Section 19 of Article I of the Texas Constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the State where each plaintiff resides, or in any other way subjecting Ethicon to impermissible multiple punishment for the same alleged wrong.

52. Plaintiff's claims for punitive damages against Ethicon cannot be sustained because an award of punitive damages under Texas law without proof of every element beyond a reasonable doubt would violate Ethicon's rights under Amendments IV, V, VI, and XIV to the United States Constitution and under Sections 9, 10, 14, and 19 of Article I of the Texas

Constitution.

- 53. Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the state of Texas and any other applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.
- 54. With respect to Plaintiff's demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts, together with all such standards applicable under the laws of Texas and any other state's law.
- 55. Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the Texas Damages Act and the Due Process Clauses of the United States and Texas Constitutions. *See*, *e.g.*, TEX. CIV. PRAC. & REM. CODE § 41.008.
- 56. Ethicon specifically pleads as to Plaintiff's claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of Texas and any state whose law is deemed to apply in this case, and under any common-law principles of Texas and any state whose law is deemed to apply in this case
- 57. Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.
 - 58. Ethicon reserves the right to assert any additional applicable defenses and matters

in avoidance, which may be disclosed during the course of additional investigation and

discovery.

IV. DEMAND FOR JURY TRIAL

59 Pursuant to Rule 216 of the Texas Rules of Civil Procedure, Defendant Ethicon,

Inc. requests that this matter be heard by a jury.

V. PRAYER

60. Ethicon respectfully requests that the Court grant its Motion to Transfer Venue

and transfer this case to Harris County, Texas. Alternatively, Ethicon respectfully requests that

the Court enter a judgment that: (i) Plaintiff take nothing on his claims against Defendant; (ii) all

of Plaintiff's claims and causes of action against Defendant be dismissed with prejudice; and (iii)

Defendant recover from Plaintiff costs of court incurred by Defendant. Defendant further

respectfully requests such other and further relief, general and special, at law or in equity, to

which they may be justly entitled.

Dated: February 23, 2017.

Respectfully submitted,

THOMPSON & KNIGHT LLP

By: /s/ Timothy E. Hudson
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ATTORNEYS FOR DEFENDANT ETHICON, INC.

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically on February 23, 2017, and was therefore served electronically on all known counsel of record.

/s/ Timothy E. Hudson
Timothy E. Hudson

040752 000297 19102853.3

EXHIBIT A-11

Details Page 1 of 5

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 64 of 68 PageID 82

Case Information

DC-17-01163 | JOSEPH MACALUSO vs. ETHICON INC, et al

Case NumberCourtFile DateDC-17-0116395th District Court01/30/2017Case TypeCase Status

OPEN

Party

OTHER (CIVIL)

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https://courtsportal.dallascounty.org/DALLASPROD/Home/WorkspaceMode?p=0

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 65 of 68 PageID 83

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Events and Hearings

01/30/2017 NEW CASE FILED (OCA) - CIVIL

Details Page 3 of 5

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 66 of 68 PageID 84

01/30/2017 ORIGINAL PETITION ▼ POP.pdf 01/30/2017 CASE FILING COVER SHEET ▼ Civil Cover Sheet.pdf 01/30/2017 REQUEST FOR SERVICE ▼ Letter Requesting Service.pdf 01/30/2017 ISSUE CITATION ▼ **ISSUE CITATION** ISSUE CITATION Comment 9214 8901 0661 5400 0102 2434 55 HOUSTON // 9214 8901 0661 5400 0102 2445 06 ETHICON 01/31/2017 REQUEST FOR SERVICE ▼ Payment of additional 2 dollars.pdf 02/03/2017 CITATION ▼ **Anticipated Server CERTIFIED MAIL** Anticipated Method **Actual Server CERTIFIED MAIL** Returned 02/10/2017 **Anticipated Server CERTIFIED MAIL Anticipated Method** Actual Server **CERTIFIED MAIL** Returned 02/10/2017 Comment CERT MAIL KK 02/07/2017 NOTE - ADMINISTRATOR ▼ Comment Set for initial dismissal: March 30, 2017. Notice faxed to counsel.

Details Page 4 of 5

Case 3:17-cv-00542-M Document 1-3 Filed 02/24/17 Page 67 of 68 PageID 85

02/10/2017 RETURN OF SERVICE ▼

ETHICON

Comment

CIT EXEC 2/9/17 TO ETHICON INC CERT MAIL

02/10/2017 RETURN OF SERVICE ▼

HOUSTON NORTHWEST OPERATING CO

Comment

CIT EXEC 2/9/17 TO HOUSTON NORTHWEST OPERATING CO LLC DBA CERT MAIL

02/13/2017 ORIGINAL ANSWER - GENERAL DENIAL -

2.13.17 OA - Macaluso.pdf

02/23/2017 ORIGINAL ANSWER - GENERAL DENIAL ▼

Original Answer - General Denial

02/23/2017 MOTION - TRANSFER - CHANGE OF VENUE ▼

MOTION - TRANSFER - CHANGE OF VENUE

03/30/2017 DISMISSAL FOR WANT OF PROSECUTION ▼

Judicial Officer

MOLBERG, KEN

Hearing Time

9:00 AM

Financial

MACALUSO, JOSEPH

Total Financial Assessment

\$489.00

Details Page 5 of 5

Total Pa	ayments and Credits			\$489.00
, ,	Transaction Assessment			\$487.00
1/31/2017	CREDIT CARD - TEXFILE (DC)	Receipt # 6010- 2017-DCLK	MACALUSO, JOSEPH	(\$487.00)
1/31/2017	Transaction Assessment			\$2.00
	CREDIT CARD - TEXFILE (DC)		MACALUSO, JOSEPH	(\$2.00)

Documents

POP.pdf

Civil Cover Sheet.pdf

Letter Requesting Service.pdf

Payment of additional 2 dollars.pdf

ISSUE CITATION

ISSUE CITATION

ETHICON

HOUSTON NORTHWEST OPERATING CO

2.13.17 OA - Macaluso.pdf

Original Answer - General Denial

MOTION - TRANSFER - CHANGE OF VENUE